Message Text

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E.O. 11652: N/A

TAGS: TGEN, UK

SUBJECT: QUERY ON STRONTIUM CHLORIDE

REFERENCE: LONDON 4353 PASS SCIENCE COUNSELOR

1. FDA ADVISES THAT: (A) STRONTIUM CHLORIDE, WHILE NOT AN "APPROVED NEW DRUG", IS NEVERTHELESS MARKETED CURRENTLY IN THE U.S. IT IS USED IN AN OTC (OVER-THE-COUNTER) TOOTH-PASTE "SENSODYNE" WHICH IS RECOMMENDED FOR DENTAL CARE IN PERSONS WITH "SENSITIVE TEETH" (WHERE THE GUMS HAVE RECEDED FROM THE TOOTH/TEETH LEAVING AN EXPOSED AREA OF DENTIN). THE PRODUCT IS CURRENTLY BEING REVIEWED WITH OTHER OTC DENTAL PRODUCTS BY THE "OTC DENTIFRICE AND DENTAL CARE AGENT REVIEW PANEL". A REPORT (PRELIMINARY) SHOULD ISSUE SOMETIME THIS SUMMER AND WILL BE PUBLISHED IN THE FEDERAL REGISTER AS A "PROPOSED MONOGRAPH".

2. (B) SODIUM FLOURIDE, AS AN INGREDIENT, IS CURRENTLY MARKETED IN GLEEM TOOTHPASTE. GLEEM IS THE SUBJECT OF AN UNCLASSIFIED

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"APPROVED NEW DRUG APPLICATION" AND, THUS, THE PRODUCT AND ITS ACTIVE INGREDIENT, SODIUM FLOURIDE, HAVE BEEN APPROVED THROUGH THE NEW DRUG APPROVAL PROCESS AS SAFE AND EFFECTIVE FOR THE PREVENTION OF CARIES FORMATION. SODIUM FLOURIDE

IS ALSO USED IN GELS, MOUTHWASHES ETC. FOR SIMILAR PURPOSES.

3. IN SUMMARY THEN NEITHER STRONTIUM CHLORIDE NOR SODIUM FLOURIDE ARE BANNED IN THE U.S. AND ARE INGREDIENTS CURRENTLY MARKETED IN A VARIETY OF DENTAL CARE PRODUCTS. COOPER

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